



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,931	10/22/1999	WOLFGANG-REINHOLD KNAPPE	BMID9826US	2537

7590 03/28/2005

RICHARD T KNAUER  
ROCHE DIAGNOSTICS CORPORATION  
9115 HAGUE ROAD BLDG D  
PO BOX 50457  
INDIANAPOLIS, IN 462500457

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/426,931

Applicant(s)

KNAPPE, WOLFGANG-REINHOL

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-48 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61 and 62 is/are allowed.
- 6) ☒ Claim(s) 41-43, 46-48 and 56-60 is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2005 has been entered.

### *Withdrawal of Rejections from Previous Office Action*

- The obviousness rejection over Good et al in view of Dreyful is withdrawn in view of Applicants' amendment to recite each layer having reagents and the overlay directly contacting each layer.

### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 41-43, 46-48 and 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,846,837 to Thym et al in view of US patent 2,063,987 to Dreyfus.

Thym et al disclose a diagnostic device comprising a support layer (2), a detection layer (3) and a network layer (4), which is an overlay layer. The detection layer (3) contains reagents which can be observed and measured and the signal formation is visible through the supporting layer, which may be transparent (col. 6, line 64 – col. 7, line 3). The device may have two

Art Unit: 1743

detection layers (3), as recited in claims 46 and 59 (col. 11, lines 21-22). The network (4) is a material that is not capillary active, such as monofilament fabrics. The monofilament fabric may be made hydrophilic by treatment with a wetting agent. The network overlay (4) is attached to support layer (2) by means of spacers (10). Cover layers (5) are attached to the support (2) and the network overlay (4) in a manner such that they cover the area of the network overlay that extends beyond the detection layer (3). With respect to claims 47, 47 and 58, Thym et al disclose that where large volumes of sample are disposed onto the sample application area (7), the void spaces under cover layers (5) are filled first, so that no excess fluid is taken up by the detection layer. With respect to claim 56, Thym et al disclose that the network overlay (4) extends beyond detection layer (3) and is covered by cover layers (5), as shown in figure 4 of the reference.

Thym et al differ from the instant invention in that while the reference teaches that the network overlay (4) may be treated with a wetting agent, no particular wetting agent is disclosed.

Dreyfus '987 teaches that fatty acid sarcosine are good wetting agents. At col. 2, lines 20-30, Dreyfus teaches higher fatty acid radicals, such as those containing more than 8 carbon atoms are suitable. Dreyfus specifically teaches the oleic acid radical as an example where valuable results may be obtained. The fatty acid sarcosines are particularly used in wet treating textile materials such as fabric-like material.

It would have been obvious to one of ordinary skill in the art to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Thym et al to provide better wetting properties to the fibrous pads and allow sample to be up taken more efficiently.

Art Unit: 1743

***Allowable Subject Matter***

4. Claims 61 and 62 are allowed.
5. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach two overlay elements, as recited in claims 44 and 61, wherein the overlay elements face one another and whose parts are displaceable from the test strip.

***Response to Arguments***

6. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256.


The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lic

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700